National Home Infusion Foundation

Standard Definitions for Patient Outcome Data Elements

Outcome: Adverse Drug Reaction (ADR)

Data Element	Definition	Additional Information/ Examples
Adverse Drug Reaction	An undesirable response, other than a known side effect, to the administration of an infused drug that compromises efficacy, and/or enhances toxicity.	***Known side effects*** would include commonly reported mild and moderate reactions listed in the FDA approved drug labeling or reported in published clinical studies. The following are examples of known side effects that would not be considered an ADR according to this definition: • A patient experiences red man syndrome during the administration of vancomycin, and the symptoms are resolved with simple therapeutic treatments. • A patient experiences a drop in blood pressure during an IgG infusion, which is resolved by slowing the infusion rate. • A parenteral nutrition patient experiences mild symptoms of low blood sugar upon discontinuation of the infusion, which is resolved by lengthening the taper period. The following are examples of ADRs: • A patient requires hospitalization after experiencing an anaphylactic reaction to an infused medication. • A patient experiences unexplained acute renal failure after receiving several doses of an infused medication.

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Data Element	Definition	Additional Information/ Examples
Adverse Drug Reaction Classification System	Serious: Any adverse event resulting in any of the following outcomes: Death, a life-threatening condition, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Severe: An experience that requires therapeutic intervention. If hospitalization is required for treatment it becomes a serious adverse event. Moderate: An experience that is alleviated with simple therapeutic treatments. Mild: An experience that is usually transient and requires no special treatment or intervention. (WHO Technical Report 498, 1972)	• All "Serious" and "Severe" events are ADRs. • "Moderate" and "Mild" events may be ADRs if they are unexpected and unpreventable.
Adverse Drug Reaction Interventions	Select all the interventions performed in response to the ADR: • Provided additional teaching/ education • Dose held • Infusion therapy order changed • Infusion therapy discontinued • Adjunctive treatment administered • Unscheduled nursing visit performed • Unplanned hospitalization • Emergency department use • Unscheduled labs drawn • Equipment repaired or replaced • FDA MedWatch Report submitted • Other: _____	

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Data Element	Definition	Additional Information/ Examples
Adverse Drug Reaction Outcomes	Select the outcome that best describes the impact of the ADR on the home infusion episode. • Continuation of home infusion services with no interruption • Interruption of services, followed by resumption of care with therapy changes • Interruption of services, followed by resumption of care without therapy changes • Home Infusion services discontinued	• An ***interruption in therapy*** occurs when the scheduled dose of an infusion medication is significantly delayed or missed.

BACKGROUND

The Standard Definitions for Patient Outcome Data Elements are presented by the National Home Infusion Foundation (NHIF) to home and specialty infusion providers for use when collecting data related to patient events as part of ongoing quality improvement activities. These definitions were developed by a volunteer-based Outcomes Task Force comprised of individual provider and business-firm members committed to the utilization of quality data to advance the infusion industry. Standardized definitions will allow providers to engage in industry-wide benchmarking and research activities, generating the necessary data for demonstrating the quality and value associated with administering infused medications in the home setting. Providers are encouraged to adopt the NHIF Patient Outcome Definitions to become eligible for participation in future industry-wide quality data initiatives.

IMPLEMENTATION CONSIDERATIONS

Providers may use additional, more detailed interventions than those proposed in the above *"Adverse Drug Reaction"* definition. The NHIF data elements are designed to consolidate data into broader categories to facilitate comparisons across different providers. Providers may wish to collect more specific data at an organizational level; however, the more detailed data would be mapped to the broader category for national reporting purposes.

NHIF recognizes that individual providers use a variety of software systems and processes to collect data and understands that differences exist with regard to the clinical terminology used today. NHIF knows that some adaptation may need to occur to achieve standardization with these outcome data elements; however, the Outcomes Task Force made every effort to develop data definitions that are broad enough to accommodate variations in software and data collection processes between providers.

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REPORTING DATA

The National Home Infusion Foundation (NHIF) is administering industry-wide benchmarking programs that utilize the Patient Outcome Data Elements proposed by NHIF. Providers that have adopted the standard NHIF definitions will be able to participate in benchmarking initiatives. Participation in benchmarking is highly encouraged as a means of evaluating one's performance compared to industry norms and standards. Benchmarking is a well-established method of improving quality, demonstrating value, and identifying best practices.

QUESTIONS/ COMMENTS

Questions or comments regarding the Standard Definitions for Patient Outcome Data Elements should be directed to NHIFdata@nhia.org.

For additional information about the NHIF Benchmarking Initiatives, please visit the NHIF website at http://bit.ly/nhif-benchmarking-initiatives.

References:

Code of Federal Regulations Title
21CFR312.32
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.32

WHO Draft Guidelines for Adverse Event Reporting and Learning Systems (World Alliance for Patient Safety) Publications of the World Health Organization